

ACETAMINOPHEN 500MG ES- acetaminophen 500mg tablet

Allegiant Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active Ingredient (in each tablet)

Acetaminophen 500 mg

Purpose

Pain reliever/fever reducer

Uses

temporary relief of minor aches and pains associated with

- common cold
- headache
- toothache
- muscular aches
- backache
- arthritis
- menstrual cramps
- temporarily reduces fever

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- if you are allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription).

If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

liver disease

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- symptoms do not improve
- pain gets worse or lasts for more than 10 days
- pain get worse or lasts more than 5 days in children under 12 years
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- redness or swelling is present
- a rare sensitivity reaction occurs
- **You may report side effects to 1-888-952-0050**

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children

Keep out of reach of children. In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not use more than directed (see overdose warning)**
- **adults and children 12 years and over:** take 2 tablets every 4 to 6 hours. Do not take more than 8 tablets in 24 hours.
- **Do not use more than 10 days unless directed by a doctor**
- **children under 12 years of age:** do not use this extra strength product; this will provide more than the recommended dose (overdose) and could cause serious health problems.

Other information

- store between 20°-25°C (68°-77°F)
- do not use if imprinted safety seal under cap is broken or missing

Inactive ingredients

corn starch, povidone, pregelatinized starch, sodium starch glycolate, stearic acid

Principal Display Panel



Acetaminophen 500mg

ACETAMINOPHEN 500MG ES

acetaminophen 500mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69 168-0 11
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)			Acetaminophen	500 mg
Inactive Ingredients				
Ingredient Name				Strength
STARCH, CORN (UNII: O8232NY3SJ)				
POVIDONE (UNII: FZ989GH94E)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
Product Characteristics				
Color	WHITE (White)		Score	no score
Shape	ROUND (round)		Size	12mm
Flavor			Imprint Code	AZ;011
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-011-50	1 in 1 CARTON	04/15/2016	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-011-40	1 in 1 CARTON	04/15/2016	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL		part343	04/15/2016	

Labeler - Allegiant Health (079501930)